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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,329	03/16/2001	Marie Christine Bissery	03806.0493	5359

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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 08/13/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/809,329	Applicant(s) BISSERY, MARIE CHRISTINE	
	Examiner Michael C. Henry	Art Unit 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 and 3</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

Claims 1-20 are pending in application

#### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### *Information Disclosure Statement*

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1<sup>and 9-12</sup> are rejected under 35 U.S.C. 102(b) as being anticipated by Furata et al. (Jpn J Cancer Chemother 18 (3): 393-402, 1991).

In claim 1, applicant claims a therapeutic pharmaceutical composition, comprising an effective amount of camptothecin, or a camptothecin derivative, in combination with an effective amount of a topoisomerase II inhibitor for the treatment of solids tumors.

Furata et al. disclose applicant's claimed, therapeutic pharmaceutical composition, comprising an effective amount of camptothecin derivative (CPT-II), in combination with an effective amount of a topoisomerase II inhibitor (adriamycin or doxorubicin) for the treatment of tumors (see summary or abstract and tables). The applicant's composition of claims 2-7, 9-12 is also anticipated by Furata et al.

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(see summary or abstract and tables). It should be noted that claim 1-7, 9-11 are composition claims and the recitation of the intended utility of the composition is not a further limitation of the claim. The examiner gives very little weight to said intended utility.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5,8,13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furuta et al.

In claims 5 and 7, applicant claims a composition as in claim 3 and 6 respectively, wherein said antibiotic is daunomycin (claim 5) and wherein said epipodophyllotoxin is teniposide (claim 7).

Furuta et al. disclose a composition as in claim 3 and 6 respectively, wherein said antibiotic is adriamycin and wherein said epipodophyllotoxin is etoposide.

The difference between applicant's claimed method and the method taught by Furuta et al. is that the applicant's antibiotic is daunomycin as compared to adriamycin and applicant's epipodophyllotoxin is teniposide as compared to etoposide. However, daunomycin and adriamycin are both well known anthracycline antibiotics or antitumor agents of very similar structure. That is, they can be considered species of the same genus. Also, the epipodophyllotoxin, teniposide and etoposide are antitumor agents that can also be considered species of the same genus.

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Furuta et al., to prepare and administer a therapeutic pharmaceutical composition, comprising an effective amount of camptothecin, or a camptothecin derivative, in combination with an effective amount of a topoisomerase II inhibitor like daunomycin (which can be considered to belong to the same genus as adriamycin (doxorubicin), for the treatment of different tumors.

One having ordinary skill in the art would have been motivated in view of Furuta et al., to prepare and administer a therapeutic pharmaceutical composition, comprising an effective amount of camptothecin, or a camptothecin derivative, in combination with an effective amount of a topoisomerase II inhibitor like daunomycin based on need, like the type and/or degree of severity of the tumor.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furuta et al.

In claim 13, applicant claims a method of treating a solid tumor, comprising administering an effective amount of camptothecin, or a camptothecin derivative, as a first agent, in combination with administration of an effective amount of a topoisomerase II inhibitor as a second agent, wherein the agents are administered simultaneously, semi-simultaneously, or separately.

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Furuta et al. disclose a method of treating a tumor (L 1210 leukemia), comprising administering an effective amount of a camptothecin derivative, as a first agent, in combination with administration of an effective amount of a topoisomerase II inhibitor as a second agent, wherein the agents are administered simultaneously, semi-simultaneously, or separately (see abstract and tables).

The difference between applicant's claimed method and the method taught by Furuta et al. is that the applicant's type of tumor that is treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Furuta et al., to use the method of Furuta et al. to treat various types of tumors like solid tumors, and to use antitumor agents taught by Furuta et al. that belong to the same genus as (adriamycin and daunomycin) and (teniposide and etoposide) for the treatment of different tumors, based on need, like the type and/or degree of severity of the tumor.

One having ordinary skill in the art would have been motivated in view of Furuta et al., to use the method of Furuta et al. to treat various types of tumors like solid tumors, and to use antitumor agents taught by Furuta et al. that belong to the same genus as (adriamycin and daunomycin) and (teniposide and etoposide), for the treatment of different tumors, based on need, like the type and/or degree of severity of the tumor.

It should be noted that claims 14-20 are also obvious in view of Furuta et al., and that the oral administration of the composition as recited in claim 20 is also based on need, like the type and/or degree of severity of the tumor and the subject that is treated.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307.


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The examiner can normally be reached on 8:00 am to 4:30pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703 308-4532. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

May 7, 2002

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1300